This content has been created to supplement the MCG care guidelines. MCG Health has neither reviewed nor approved the modified material.

RMHP Implantation of Intrastromal Corneal Ring Segments (INTACS)

MCG Health
Ambulatory Care
27th Edition

AUTH: RMHP-AC-5013 (AC)

Link to Codes

Clinical Indications for Procedure

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This procedure is classified as Not a Benefit for **RMHP PRIME (Medicaid)** and **CHP+** members per Colorado Department of Health Care Policy and Financing guidance. The case will be denied as Not a Benefit of the Member's Health Care Plan.

- The procedure is/was needed for appropriate care of the patient because of **ALL** of the following
  - The Member has **RMHP Individual and Family Plan (IFP) Commercial, Medicare (CareAdvantage or Dual Special Needs Plan (DSNP)** health coverage and requires the implantation of an intrastromal corneal ring segment for the reduction or elimination of myopia or astigmatism **ALL** of the following
    - The Member is twenty-one (21) years of age or older
    - The Member has a diagnosis of **keratoconus**
    - The Member cannot achieve adequate vision using contact lenses or spectacles
    - The Member's central cornea is clear
    - The Member's corneal thickness is of 450 microns or greater at the proposed incision site
    - A corneal transplantation is the only other remaining option to improve functional vision

Documentation Required

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- Ophthalmologist notes

Evidence Summary

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The use of this technology for corneal hysteresis is not covered because it is the result of a non-covered procedure.

Corneal cross-linking was approved by the FDA in April 2016 and has its own separate policy.

For individuals with keratoconus, there are several case series on intrastromal corneal implants. Boxer Wachler (2003) reported on the outcomes in 74 eyes of 50 subjects with a mean follow-up of 9 months. A total of 45% gained at least 2 lines of (BSCVA, 51% of individuals had no change, and 4% lost BSCVA. Siganos (2003) studied 33 eyes in 26 individuals at a mean follow-up of 11.3 months. In this study, 25 eyes recorded a 1- to 6-line gain in BSCVA, while 4 eyes remained unchanged and 4 eyes experienced a loss. Colin (2001) reported the 1-year results in a series of 10 individuals. The mean values for BSCVA improved progressively over time, and at the 12 month follow-up, average visual acuity was 2 lines better than baseline. Alio (2006) reported the outcomes of 13 eyes with a follow-up of 36 months in all eyes. Mean best BSCVA increased from 0.46 (20/50) preoperatively to 0.66 (20/30) postoperatively ($p \leq 0.001$). Colin and Malet (2007) reported outcomes of a 2-year follow-up study comprised of 100 eyes after INTACS implantation. At 2 years, the uncorrected visual acuity (UCVA) and BCVA improved in 80.5% and 68.3% of eyes, respectively ($p<0.001$). The proportion of eyes with a BCVA greater than or equal to 0.5 (20/40) increased from 22.0% at baseline to 51.2% and 53.7% at 1 year and 2 years, respectively ($p<0.001$). Contact lens tolerance was restored in over 80% of cases. Additional recent case series and retrospective reviews continue to show promising results for intrastromal corneal implants for the treatment of refractory keratoconus (Bedi, 2012; Ozerturk, 2012; Torquetti, 2014).

Policy History

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History Summary: 10/23/2007. Originated. 2/17/2009 Reviewed. 2/23/2010 Reviewed. 5/10/2011 Reviewed. 4/10/2012. Revised: Added corneal thickness of 450 microns to requirements. Added comment regarding non-coverage when used to treat corneal hysteresis. 11/11/2013. Reviewed by NTAG and MAC. 12/8/2014 Evidence summary revised to state that corneal cross-linking is not FDA approved, therefore is not covered. Approved by NTAG and MAC. 12/7/2015 Reviewed by NTAG and MAC. No revisions. 11/8/2016 Reviewed by NTAG and MAC. No revisions. 12/21/2017 Approved by NTAG Committee - annual review. Added description & reviewer guidance, Added FDA approval April 2016. NCD & article reviewed 12/18/2017. 2018 Annual review – approved by committees with no changes. 2019 Annual review – approved by committees with no changes. 2020 Annual review - approved by relevant committee hierarchy with no changes. 2021 Annual review by committees - no changes. 6/7/2021 - expanded description, evidence summary, references, re-confirmed fee schedule status. 4/6/2022 internal review and fee schedule/status/MCD database checks. 2022 Annual review – approved by committees with no changes. 6/16/2022 updated references, schedule review dates, no status changes.

2023 Annual review with committee approval.

Reviewer Guidance

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As of 5/10/2023 this procedure remains listed as Not A Benefit on the Health First Colorado (Medicaid) Fee Schedule . Review the appropriate document for revision before making a determination of non-coverage. As of 4/5/2023, there is no Medicare LCD or NCD, code status is A (active) on Medicare Fee Schedule indicating carrier determination.

Implantation of Intrastromal Corneal Ring Segments are not covered 1) when refractive eye surgery is specifically excluded from the benefit plan; 2) as a treatment for myopia, because it is considered refractive

eye surgery and therefore a benefit exclusion 3) when myopia can be corrected with more conservative measures such as glasses or contact lenses.

For patients with myopia, astigmatism, or keratoconus, implantation of intrastromal corneal ring segments to enable the patient to successfully wear soft or hard contact lenses is considered refractive eye surgery and therefore is a benefit exclusion.

Implantation of intrastromal corneal ring segments following LASIK, PRK (photorefractive keratectomy) or other refractive surgical procedures is considered not covered. A small percentage of patients may have problems after these procedures (i.e., the procedure may not fully correct the refractive error, the procedure can result in a condition known as ectasia (a forward bulging of the cornea), or the initial full correction may regress to only a partial correction). Treatment of side effects or complications as a result of a non-covered procedure (refractive eye surgery) is a benefit exclusion under most benefit plans.

Implantation of intrastromal corneal ring segments is considered investigational for all other conditions not listed as a Clinical Indication for Procedure.

Description

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Keratoconus

Keratoconus is a progressive bilateral dystrophy that is characterized by paracentral steepening and stromal thinning that impairs visual acuity. Initial treatment often consists of hard contact lenses. A penetrating keratoplasty (that is, corneal grafting) is the next line of treatment for those individuals who develop intolerance to contact lenses. While visual acuity is typically improved with a keratoplasty, there is an associated risk of perioperative complications, long-term topical steroid use is required and endothelial cell loss occurs over time, which is a particular concern in younger individuals. As an alternative, a variety of keratorefractive procedures have been attempted, which are broadly divided into subtractive and additive techniques. Subtractive techniques include photorefractive keratectomy or LASIK but, in general, results of these techniques have been poor. Implantation of intrastromal corneal ring segments (INTACS Prescription Inserts) represents an additive technique where the implants are intended to reinforce the cornea, prevent further deterioration and potentially obviate the need for a penetrating keratoplasty. This technique has primarily been investigated in individuals in whom the cornea has remained transparent and who are intolerant to contact lenses.

Intrastromal corneal ring segments (ICRS) consist of micro-thin soft plastic inserts of variable thickness that are placed in the periphery of the cornea. Intrastromal corneal ring segments have been investigated as a means of improving vision in diseases such as keratoconus, pellucid marginal degeneration, and for refractive surgery to correct mild myopia and astigmatism following penetrating keratoplasty.

Intrastromal corneal ring segments are flexible, cresent shaped rings of polymethylmethacrylate that are placed in the periphery of the cornea. An incision is made in the cornea and channels are created in it by rotating a lamellar dissector or by using a femtosecond laser. One or two corneal implant segments are introduced into each channel, and various implants with a range of implant thicknesses are available for different degrees of correction. They affect the refraction in the eye by physically changing the shape of the cornea, thereby correcting the irregular corneal shape. If required these implants can be removed at a later date.

References

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Boxer Wachler BS, Christie JP, Chandra NS, et al. INTACS for keratoconus. Ophthalmology. 2003; 110(5):1031-1040.

Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. Am J Ophthalmol. 2003; 135(1):64-70.

Bedi R, Touboul D, Pinsard L, Colin J. Refractive and topographic stability of Intacs in eyes with progressive keratoconus: five-year follow-up. J Refract Surg. 2012; 28(6):392-396.

Colin J, Cochener B, Savary G, et al. INTACS inserts for treating keratoconus. Ophthalmology. 2001; 108(8):1409-1414.

Colin J, Malet FJ. Intacs for the correction of keratoconus: two-year follow-up. J Cataract Refract Surg. 2007; 33(1):69-74.

Bedi R, Touboul D, Pinsard L, Colin J. Refractive and topographic stability of Intacs in eyes with progressive keratoconus: five-year follow-up. J Refract Surg. 2012; 28(6):392-396.

U.S. National Library of Medicine, Medline Plus, Refractive Errors: https://medlineplus.gov/refractiveerrors.html

Colorado Department of Healthcare Policy and Financing (HCPF), Provider Rates and Fee Schedules, the current Health First Colorado Fee Schedule, effective 1/1/2023 reviewed 5/10/2023 continues status of Not a Benefit. (No CHP+ guidance available from 2021 forward, use this same Fee Schedule for CHP+; Not a Benefit.

Novitas Solutions Medicare Jurisdiction H (Providers in AR, CO, LA, MS, NM, OK, TX, Indian Health & Veteran Affairs) Part B Fee Physician's Fee Schedule, status A & priced, "carriers remain responsible for coverage decisions in the absence of a national Medicare policy" reviewed 4/5/2023.

Codes

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